GS1 US

Healthcare

Guidance for Pharmaceutical Products Marked with Both UPC-A and GS1 DataMatrix

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1 Introduction

1.1 Overview

Many pharmaceutical products are marked with a UPC-A barcode to satisfy U.S. retail Point of Sale (POS) requirements and/or the _U.S. Food and Drug Administration (FDA) Barcode Rule_.[1] However, starting in 2017, the _U.S. Drug Supply Chain Security Act (DSCSA)_ requires pharmaceutical products to be marked with a two-dimensional (2D) data matrix barcode[2] carrying the product's National Drug Code (NDC)[3], Serial Number, Lot Number, and Expiration Date.[4] As a result, the industry is experiencing instances where products are marked with two barcodes: a UPC-A _(for POS and/or the FDA Barcode Rule)_ and a GS1 DataMatrix _(for DSCSA)_.

Industry has noted certain challenges with this practice, including improperly formed Global Trade Item Numbers (GTINs) encoded in the barcodes, and confusion for downstream trading partner scanning systems and transactional databases. In response, GS1 Healthcare US® prepared this guide to assist U.S. pharmaceutical trading partners with these challenges. To that end, this document provides guidance about the use of UPC-A and GS1 DataMatrix together, including assignment and encoding guidance for suppliers, and system and personnel guidance for recipients.

Note: This guideline does not provide any guidance or advice regarding regulatory compliance. Suppliers need to consult with their regulatory compliance teams to determine what is required for their specific company or products pursuant to the U.S. FDA Barcode Rule and/or DSCSA, and whether the concepts presented in this guideline apply to their products.

1.2 Audience

The prime audience for this document includes pharmaceutical manufacturers, distributors, retail pharmacies, hospital receivers, and clinicians.

1.3 Scope

Not all pharmaceutical products require two barcodes. Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company's legal counsel or compliance team (regulatory or quality) for more specific information about statutory and regulatory requirements and whether the concepts presented in this guideline apply to your products.

1.4 Normative References

This guide is based on the _GS1 General Specifications_ and the _GS1 US Implementation Guideline: Applying GS1 Standards for the U.S. Drug Supply Chain Security Act (DSCSA)_.

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[1] U.S. Department of Health and Human Services. Food and Drug Administration (FDA). _Bar Code Label Requirement for Human Drug and Biological Products_. April 26, 2004. ("U.S. FDA Barcode Rule")
[2] _Drug Supply Chain Security Act (DSCSA)_, Sec. 582 (a)(9)[A][i].
[3] In the GS1 System, the GS1 Global Trade Item Number® (GTIN®) is used to represent the NDC.
[4] _Drug Supply Chain Security Act (DSCSA)_, Sec. 581 (14), Sec. 582 (b)(2)(A).

2   Use of the UPC-A Barcode for Pharmaceutical Products

UPC-A is a GS1 Standards-based linear barcode. It holds a maximum of 12 digits, and therefore can only carry a 12-digit GTIN. It cannot carry any secondary information like expiration date or serial number. UPC-A can be used to mark pharmaceutical products to support either retail Point-of-Sale and/or the *U.S. FDA Barcode Rule*:

- Retail distribution channels require products to be marked with an EAN®/UPC barcode to support Point-of-Sale (POS) applications. UPC-A is part of the EAN/UPC family of symbols, and commonly used to mark products sold in U.S. retail channels.

- The U.S. FDA Barcode Rule requires certain drug products to be marked with a linear barcode that that contains the product's NDC. UPC-A is a linear barcode that may be used for the Barcode Rule.[5]

- Pharmaceutical manufacturers should no longer use an "N" in the HRI of a UPC-A barcode. The "N" was removed from the *GS1 General Specifications* in January 2017 because:

  1. It was an obsolete structure for GTINs, and

  2. Human Readable Interpretation (HRI) rules specify that HRI are to be an exact and accurate representation of what was encoded in the barcode (with the exception of the parentheses), and there was no "N" encoded in the barcode.

Figure 6-3 Example of a UPC-A Barcode Used for POS and/or U.S. FDA Barcode Rule

3   DSCSA and the Data Matrix Requirement

Starting in 2017, the DSCSA requires pharmaceutical products to be marked with a two-dimensional (2D) data matrix barcode carrying the NDC, Serial Number, Lot Number, and Expiration Date. Manufacturers using GS1 Standards for DSCSA use the GS1 DataMatrix.

The GS1 DataMatrix is a 2D barcode. Unlike UPC-A, GS1 DataMatrix has extended capacity and can carry the GTIN plus secondary information. Therefore, it can carry all four DSCSA-required data elements (i.e. NDC, Serial Number, Lot Number, and Expiration Date).

## 4   Why Mark Products with Both UPC-A and GS1 DataMatrix

U.S. FDA Barcode Rule requires products be marked with a linear barcode carrying the product NDC. DSCSA requires products be marked with a data matrix barcode carrying NDC, Serial Number, Lot Number, and Expiration Date. Neither UPC-A nor GS1 DataMatrix can satisfy both sets of requirements:

- UPC-A can be used for the U.S. FDA's linear barcode requirement. However, it cannot be used for DSCSA because it is not a data matrix symbol and because its limited capacity cannot accommodate all four DSCSA-required data elements (i.e. NDC, Serial Number, Lot Number, and Expiration Date).

- GS1 DataMatrix can be used for DSCSA serialization requirements. However, as a 2D barcode, it cannot be used for the U.S. FDA's linear barcode requirement.

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[5] 21 CFR 201.25

Marking pharmaceutical products with both barcodes satisfies both sets of requirements. Thus, the intersection of retail channel POS requirements and/or the U.S. FDA Barcode Rule with DSCSA serialization requirements has created an environment where some pharmaceutical products are marked with two barcodes: a UPC-A *(for POS and/or the FDA Barcode Rule)* and a GS1 DataMatrix *(for DSCSA)*. **The key to this approach is that the GTIN in the UPC-A must be the same as the GTIN in the GS1 DataMatrix.**

Figure 4-1 Product GTIN (NDC) Encoded in Both UPC-A and GS1 DataMatrix

GTIN 00314141999995
EXP 120125
LOT 987654321GFEDCBA
SN 10000000234

UPC-A   **GS1 DataMatrix**
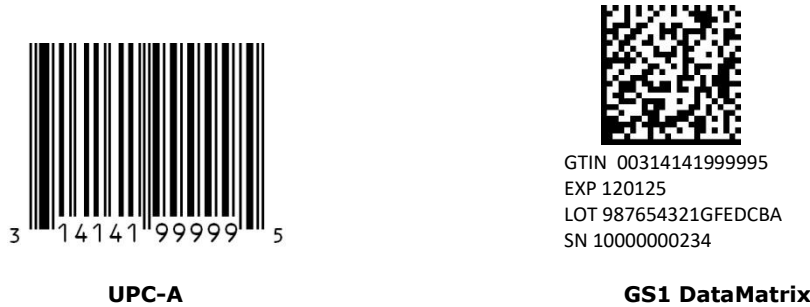
5   Key Concepts About this Approach

- The UPC-A will carry the GTIN (representing the NDC) for the U.S. FDA Barcode Rule and/or U.S. retail POS requirements.

- The GS1 DataMatrix will carry the GTIN (representing the NDC), Serial Number, Lot Number, and Expiration Date for DSCSA serialization requirements.

- The GTIN in the UPC-A must be the same as the GTIN in the GS1 DataMatrix.

- Manufacturers/suppliers will need to follow GS1 Standards to correctly implement product marking with both UPC-A and GS1 DataMatrix barcodes. (The specific process is defined *below*.)

- Recipients of products marked with both UPC-A and GS1 DataMatrix barcodes will need to review scanning systems and train personnel to understand the different symbols. (Specific guidance provided *below*.)

6   Guidance for Manufacturers/Suppliers

6.1   Step-by-Step Instructions

If you need to mark a product with both a UPC-A barcode and a GS1 DataMatrix, follow the steps below order to assure that the GTIN encoded in both barcodes is the same:

1. Assign a GTIN-12 to identify the product.

2. Create the UPC-A linear barcode using the GTIN-12.

3. Pad the GTIN-12 with two leading zeros to create a "GTIN-12 in 14-digit format."

GTIN-12	**314141999995**
GTIN-12 in 14-digit format	**00314141999995**

4. Create the GS1 DataMatrix barcode using the "GTIN-12 in 14-digit format."

   □ Note: for DSCSA purposes, you will also encode the serial number, lot number, and expiration date in the GS1 DataMatrix in addition to the GTIN.

5. When storing GTIN-12s in databases, store them in the 14-digit format.

6.2 Standards Rationale

■ Per the standards, GTINs can be <u>assigned</u> as 8 digits, 12 digits, 13 digits, <u>or</u> 14 digits in length.

■ However, within the U.S. pharmaceutical supply chain, the 12-digit GTIN (known as the "GTIN-12") and the 14-digit GTIN (known as the "GTIN-14") are predominantly used.

   □ Choice of GTIN structure can be based on various factors, including product type, product size, retail versus non-retail needs, packaging material, etc.

■ The UPC-A holds a maximum of 12 digits, and therefore GTIN-12s are assigned to products that need to be marked with a UPC-A.

■ The GS1 DataMatrix requires the GTIN to be in a format that is 14 digits long. To accommodate that requirement, GTINs of less than 14-digits can be padded with leading zeros for encoding (as shown above).

■ **This cannot be done in the opposite direction** (i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a "GTIN-14 in a 12-digit format") because GTIN-12 and GTIN-14 are completely different structures and it will cause errors.

   □ GTIN-14 is a numerical string comprising <u>four</u> distinct segments: Indicator Digit, GS1 Company Prefix, Item Reference, and a Check Digit.

      - The Indicator Digit in the first position is a numeric value from <u>1 to 8</u> that identifies packaging level. Therefore, a true GTIN-14 has a digit other than "0" in the 1st position.

      - Because Check Digits are calculated based on the <u>value and position</u> of each digit in a GTIN, removing the first two digits from GTIN-14 would create an entirely different GTIN.

   □ GTIN-12 is a numerical string comprising <u>three</u> distinct segments: U.P.C. Company Prefix, Item Reference, and a Check Digit.

      - The GTIN-12 does not include an Indicator Digit. This is why padding with leading zeros is permissible (i.e., because zero is not a valid Indicator Digit, systems interpreting a 14-digit GTIN string recognize that a "00" in the 1st and 2nd position means it is a GTIN-12).

      - Thus, a GTIN-12 remains a GTIN-12 whether it is in its assigned 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a "GTIN-12 in a 14-digit format." It is not a GTIN-14.

■ Therefore, when a product needs to be marked with a UPC-A, it is assigned a GTIN-12 (not a GTIN-14) in order to preserve the manufacturer's ability to represent the same GTIN in a 12-digit UPC-A as well as in any barcode that requires a 14-digit format (e.g., GS1 DataMatrix).

7 Guidance for Recipients of Products with Both UPC-A and GS1 DataMatrix

■ Verify that your databases, tables, and systems have properly-formatted GTIN fields.

   □ A GTIN should always be stored in databases and represented software applications as 14 digits by adding leading zeros as necessary to total 14 digits.

   □ In order to preserve any leading zeros that may be present, GTIN fields should always be formatted as a <u>text</u> field (not numeric), right-justified, and zero-filled to the left.

- □ This will help assure that a product's GTIN is properly recorded and aligned in your systems whether read from the UPC-A or the GS1 DataMatrix.

- ■ Assess scanning systems in preparation for data matrix barcodes.

  - □ Traditional laser barcode scanners (i.e., those used for linear barcodes like the UPC-A) cannot read data matrix barcodes. Data matrix barcodes require camera-based scanners (which can read both linear and 2D/data matrix barcodes).

  - □ Assess scanning systems that will need to read data matrix barcodes to assure that the appropriate scanners are in place, and that the system is setup to record the additional data (e.g., expiration date, lot, and serial number).

  - □ Prior to purchasing barcode scanning equipment, it is recommended that you consult the *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria*. This document was prepared by GS1 US to assist members of the U.S. healthcare supply chain in evaluating the various barcode scanning equipment options on the market, and selecting the equipment that best fits their needs.

- ■ Recipients of pharmaceutical products marked with two barcode symbols need to educate all personnel scanning barcodes, whether they are at the receiving dock, point-of-sale, or in the healthcare facility at receiving or point-of-care.

  - □ Educate personnel to recognize the two different barcodes, understand what data encoded in each, and how to read the human-readable interpretation presented beneath the barcode (as visual backup for obtaining the encoded data). (Review the *supplier guidance above* for high-level information.)

  - □ Educate personnel about scanning procedures and scanning priorities (i.e., which barcode to scan):

    - At retail, it is expected that the UPC-A barcode will be scanned unless there is a patient safety, reimbursement, or recall reason.

    - For clinical use, it is encouraged that the GS1 DataMatrix barcode containing the full DSCSA product identifier with all four data elements (i.e. NDC, Serial Number, Lot Number, and Expiration Date) be scanned for both supply chain systems and clinical systems like electronic patient records.

- ■ There are many reasons why a barcode may not scan. Many times, it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled *Procedure for Responding to Troublesome Barcodes* to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

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